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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,484	02/17/2004	David B. Rozema	Mirus.030.16.04	2135
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			EXAMINER	
			EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,484

Applicant(s)

ROZEMA ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3-7, 10-20 are presently pending for examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 102

3. Claims 1, 3-7, 10-16 and 19-20 remain rejected under 35 U.S.C. 102(e or a) as being anticipated by Pinchuk et al. (US 2002/0107330), for the reasons of record.
4. Applicant's arguments filed 10-30-07 have been fully considered but they are not persuasive.
5. According to Applicants, for an amine to be reversibly modified, reversal of the modification must restore the amine (see Applicant's specification, page 3, lines 4-7 and Figure 1). Contrary to Applicant's assertions, the features upon which Applicants relies upon, namely that the amine is restored after reversal of the modification, is not recited in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
6. Moreover, Applicant's have provided a description of what Applicant believes is the mechanism by which S-nitroso-thiol modifications function to attach functional groups to the disclosed polymers (which includes polyvinyl ether). Applicant's description is not representative of the full scope of possible mechanisms by which the S-nitrothiol groups can function to release therapeutic groups with oppositely charged

functional groups from modified polyamines. Contrary to Applicant's assertions and absent evidence to the contrary, the polyvinyl ether polymers comprising the thiol based modifications taught by Pinchuk et al. read on the pH labile modifications recited in the instant claims.

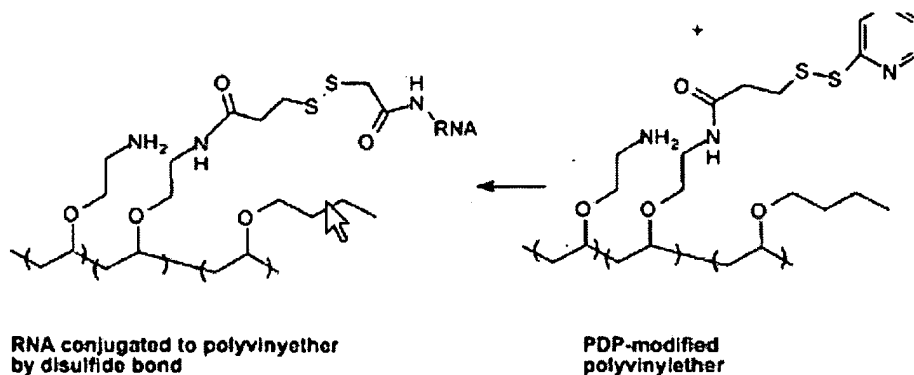
7. Claims 1-5, 7-15, 17, and 19-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (US 20010036926), for the reasons of record; Claims 1-5, 7-15, 17 and 19-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al. (US 7,087,770), for the reasons of record; Claims 1-5, 7-15, and 17-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. in view of Blazyk (WO 200160162 A2; see disclosure of US 20040249122 A1); and Claim 18 remains rejected on the ground of nonstatutory obvious-type double patenting as being unpatentable over Wolff et al. in view of Blazyk (WO 200160162 A2), for the reasons given above, and in the rejection under 35 USC 103(a) over Wolff et al. in view of Blazyk.

8. Applicant's arguments filed 10-30-2007 have been fully considered but they are not persuasive. According to Applicants, for an amine to be reversibly modified, reversal of the modification must restore the amine (see Applicant's specification, page 3, lines 4-7 and Figure 1). Contrary to Applicant's assertions, the features upon which Applicants relies upon, namely that the amine is restored after reversal of the modification, is not recited in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Applicants traverse the instant rejection on the grounds that the reversible disulfide linkages taught by Wolff et al. leaves a thiol group and not an amine.

10. Contrary to Applicant's assertions, as stated in the prior Office action, Wolff et al. teach that "[t]he monomers used for polymerization can also contain **chemical moieties that can be modified** before or after the polymerization including (but not limited to) **amines** (primary, secondary, and tertiary), amides, carboxylic acid, ester, hydroxyl, hydrazine, alkyl halide, aldehyde, and ketone. (see paragraph [0103]). Polyethyleneimine and polylysine were used in specific examples to form complexes with nucleic acid via a disulfide linkage, see examples 4 and 5. Therefore, contrary to Applicant's assertions, the teachings of Wolff et al. read on the instant claims as amended.

11. Moreover, Applicant's own specification at Figure 3, describes what Applicants consider to be the reversible modification of a polyvinylether amine:



It is clear that Applicants contemplated the use of the modification which incorporate a disulfide linkage within the scope of the reversible modifications encompassed by the instant claims.

Double Patenting

12. Claims 1-5, 7-15, 17 and 19-20 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,087,770, for the reasons of record.

Applicant's arguments filed 10-30-07 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Wolff et al. does not teach the reversible modification of any amines or the reversible modification of a membrane active polyamine. However, as stated in the prior Office Action, contrary to Applicant's the instant claims recite wherein a transduction signal is used to transport a covalently linked molecule across a membrane of a cell. The transduction signal used is a peptide, and the molecule is a nucleic acid, the peptide is then linked to said nucleic acid via a reversible activated disulfide bond, see claims.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE